

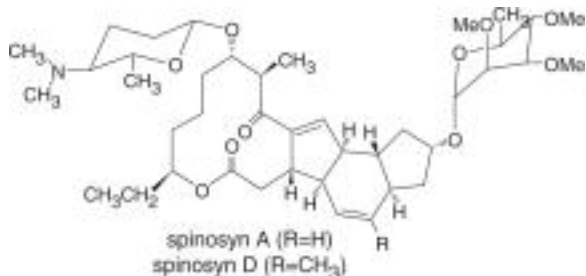
COMFORTIS - spinosad tablet, chewable
Elanco Animal Health Co

CAUTION:

Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION:

COMFORTIS chewable tablets (spinosad) are available in five chewable flavored tablet sizes for oral administration to dogs and puppies according to their weight. Each chewable tablet is formulated to provide a minimum spinosad dosage of 13.5 mg/lb (30 mg/kg). Spinosad is a member of the spinosyns class of insecticides, which are non-antibacterial tetracyclic macrolides. Spinosad contains two major factors, spinosyn A and spinosyn D, derived from the naturally occurring bacterium, *Saccharopolyspora spinosa*. Spinosyn A and spinosyn D have the chemical compositions 2-[(6-deoxy-2,3,4-tri-O-methyl- α -L-mannopyranosyl)oxy]-13-[[5-dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11, 12,13,14,16a,16b-tetradecahydro-14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7, 15-dione and 2-[(6-deoxy-2,3,4-tri-O-methyl- α -L-mannopyranosyl)oxy]-13-[[5-dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl] oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-1H-as-Indaceno[3,2-d] oxacyclododecin-7,15-dione, respectively.



INDICATIONS:

COMFORTIS chewable tablets kill fleas and are indicated for the prevention and treatment of flea infestations (*Ctenocephalides felis*) on dogs for one month.

DOSAGE AND ADMINISTRATION:

COMFORTIS chewable tablets are given orally once a month, at the recommended minimum dosage of 13.5 mg/lb (30 mg/kg).

Recommended Dosage Schedule:

Body Weight	Spinosad Per Tablet (mg)	Tablets Administered
5 to 10 lbs	140	One
10.1 to 20 lbs	270	One
20.1 to 40 lbs	560	One
40.1 to 60 lbs	810	One
60.1 to 120* lbs	1620	One

* Dogs over 120 lbs should be administered the appropriate combination of tablets.

Administer COMFORTIS chewable tablets with food for maximum effectiveness.

COMFORTIS is a chewable tablet and is readily consumed by dogs when offered by the owner just prior to feeding. Alternatively, COMFORTIS chewable tablets may be offered in food or administered like other tablet medications. COMFORTIS chewable tablets should be administered at monthly intervals.

If vomiting occurs within an hour of administration, redose with another full dose. If a dose is missed, administer COMFORTIS chewable tablets with food and resume a monthly dosing schedule.

Treatment with COMFORTIS chewable tablets may begin at any time of the year, preferably starting one month before fleas become active and continuing monthly through the end of flea season. In areas where fleas are common year-round, monthly treatment with COMFORTIS chewable tablets should continue the entire year without interruption.

To minimize the likelihood of flea reinfestation, it is important to treat all animals within a household with an approved flea protection product.

CONTRAINDICATIONS:

There are no known contraindications for the use of COMFORTIS chewable tablets.

WARNINGS:

Not for human use. Keep this and all drugs out of the reach of children.

Serious adverse reactions have been reported following concomitant extra label use of ivermectin with COMFORTIS (see **POST APPROVAL EXPERIENCE**).

PRECAUTIONS:

COMFORTIS chewable tablets are for use in dogs and puppies 14 weeks of age and older (see **ANIMAL SAFETY**).

Use with caution in breeding females (see **ANIMAL SAFETY**). Use with caution in dogs with pre-existing epilepsy (see **ADVERSE REACTIONS**). The safe use of COMFORTIS chewable tablets in breeding males has not been evaluated.

ADVERSE REACTIONS:

In a well-controlled US field study, which included a total of 470 dogs (330 dogs treated with COMFORTIS chewable tablets and 140 dogs treated with an active control), no serious adverse reactions were observed with COMFORTIS chewable tablets. All reactions were regarded as mild and did not result in any dog being removed from the study.

Over the 90-day study period, all observations of potential adverse reactions were recorded. Reactions that occurred at an incidence > 1% within any of the 3 months of observation are presented in the following table. The most frequently reported adverse reaction in dogs in the COMFORTIS chewable tablets and active control groups was vomiting. The occurrence of vomiting, most commonly within 48 hours after treatment, decreased with repeated doses of COMFORTIS chewable tablets.

Percentage of Dogs (%) with Adverse Reactions

	Month 1		Month 2		Month 3	
	COMFORTIS Chewable Tablets (N=330)	Active Topical Control (N=139 ^a)	COMFORTIS Chewable Tablets (N=282)	Active Topical Control (N=124)	COMFORTIS Chewable Tablets (N=260)	Active Topical Control (N=125)
Vomiting	12.7	12.2	7.8	3.2	5.8	4.8
Decreased Appetite	9.1	5.0	2.8	1.6	1.9	0.8
Lethargy	7.6	5.0	3.5	4.0	1.2	0.8
Diarrhea	6.7	5.0	4.3	0.8	1.2	0.0
Cough	3.9	5.0	0.4	2.4	0.0	0.0
Polydipsia	2.4	1.4	0.7	0.0	0.4	0.0
Vocalization	1.8	0.0	0.4	0.0	0.4	0.0
Increased Appetite	1.5	0.0	0.4	0.8	0.4	0.0
Erythema	1.5	0.0	0.4	0.0	0.4	0.0
Hyperactivity	1.2	1.4	0.0	0.0	0.4	0.0
Excessive Salivation	1.2	0.0	0.4	0.0	0.0	0.0

^a This number (n=139) is less than the total number of dogs in the safety population for the active control group (n=140) because one dog joined the study late and was only dosed at Month 3.

In US and European field studies, no dogs experienced seizures when dosed with COMFORTIS chewable tablets at the therapeutic dose range of 13.5-27.3 mg/lb (30-60 mg/kg), including 4 dogs with pre-existing epilepsy. Four epileptic dogs that received higher than the maximum recommended dose of 27.3 mg/lb (60 mg/kg) experienced at least one seizure within the week following the second dose of COMFORTIS chewable tablets, but no seizures following the first and third doses. The cause of the seizures observed in the field studies could not be determined.

POST APPROVAL EXPERIENCE (JUNE 2009):

The following adverse reactions are based on post-approval adverse drug event reporting. The adverse reactions are listed in decreasing order of frequency: *vomiting, depression/lethargy, anorexia, ataxia, diarrhea, pruritus, trembling, hypersalivation and seizures*.

Following concomitant extra label use of ivermectin with COMFORTIS, some dogs have experienced the following clinical signs: *trembling/twitching, salivation/drooling, seizures, ataxia, mydriasis, blindness and disorientation*.

Post approval experience continues to support the safety of COMFORTIS when used concurrently with heartworm preventatives according to label directions.

For technical assistance or to report an adverse drug reaction, call 1-888-545-5973. Additional information can be found at www.comfortis4dogs.com. For a complete listing of adverse reactions for spinosad reported to the CVM see <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm055394.htm>

MODE OF ACTION:

The primary target of action of COMFORTIS chewable tablets in insects is an activation of nicotinic acetylcholine receptors (nAChRs). Spinosad does not interact with known insecticidal binding sites of other nicotinic or GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodienes. Insects treated with spinosad show involuntary muscle contractions and tremors resulting from activation of motor neurons. Prolonged spinosad-induced hyperexcitation results in prostration, paralysis, and flea death. The selective toxicity of spinosad between insects and vertebrates may be conferred by the differential sensitivity of the insect versus vertebrate nAChRs.

EFFECTIVENESS:

In a well-controlled laboratory study, COMFORTIS chewable tablets began to kill fleas 30 minutes after administration and demonstrated 100% effectiveness within 4 hours. COMFORTIS chewable tablets kill fleas before they can lay eggs. If a severe environmental infestation exists, fleas may persist for a period of time after dose administration due to the emergence of adult fleas from pupae already in the environment. In field studies conducted in households with existing flea infestations of varying severity, flea reductions of 98.0% to 99.8% were observed over the course of 3 monthly treatments with COMFORTIS chewable tablets. Dogs with signs of flea allergy dermatitis showed improvement in erythema, papules, scaling, alopecia, dermatitis/pyodermitis and pruritus as a direct result of eliminating the fleas.

ANIMAL SAFETY:

COMFORTIS chewable tablets were tested in pure and mixed breeds of healthy dogs in well-controlled clinical and laboratory studies. No dogs were withdrawn from the field studies due to treatment-related adverse reactions.

In a dose tolerance study, COMFORTIS chewable tablets were administered orally to adult Beagle dogs at average doses of up to 100 mg/kg once daily for 10 consecutive days (16.7 times the maximum recommended monthly dose). Vomiting was seen in 5 of 6 treated dogs during the first 6 days of treatment, usually within 2.5 hours of dosing. Treated females lost weight early in the treatment period, but their weights were similar to control dogs by the end of the 24-day study. COMFORTIS chewable tablets were not associated with any clinically significant changes in hematology, blood coagulation or urinalysis parameters; however, mild elevations in ALT occurred in all dogs treated with COMFORTIS chewable tablets. By day 24, ALT values had returned to near baseline levels. Phospholipidosis (vacuolation) of the lymphoid tissue was seen in all dogs treated with COMFORTIS chewable tablets, the long-term effects of which are unknown.

In a margin of safety study, COMFORTIS chewable tablets were administered orally to 6-week-old Beagle puppies at average doses of 1.5, 4.4, and 7.4 times the maximum recommended dose at 28-day intervals over a 6-month period. Vomiting was observed across all groups, including the control. Increased vomiting was observed at elevated doses, usually within 1 hour following administration. Vomiting at all doses decreased over time and stabilized when puppies were 14 weeks of age. The average daily and total weight gains of treated dogs were smaller than control dogs and were dose dependent. COMFORTIS chewable tablets were not associated with clinically significant changes in hematology, clinical chemistry, coagulation or urinalysis parameters. Phospholipidosis (vacuolation) of the lymphoid tissue was seen in some dogs in the 4.4X group and all dogs in the 7.4X group. The long term effects of phospholipidosis are unknown. Treatment with COMFORTIS chewable tablets was not associated with any other clinically significant adverse clinical observations, gross necropsy or histopathological changes.

In a reproductive safety study, COMFORTIS chewable tablets were administered orally to female Beagles at 1.3 and 4.4 times the maximum recommended therapeutic dose every 28 days prior to mating, during gestation, and during a six-week lactation period. No treatment-related adverse effects were noted for conception rates in the dams, or for mortality, body temperature, necropsy, or histopathology findings for the dams or puppies. One dam from each treatment group experienced early pregnancy loss and one additional high dose dam aborted late term. The treated dams experienced more vomiting, especially at one hour post-dose, than the control dams. Puppies from dams treated at 1.3 times the maximum recommended therapeutic dose had lower body weights than puppies from control dams. Although puppy mortality between treated and control dams was not different, the puppies from the treated dams experienced more lethargy (4.4X group only), dehydration, weakness and felt cold to the touch (4.4X group only) than puppies from control dams.

A pilot study without a control group was conducted to analyze milk from three lactating dogs treated with an experimental formulation of spinosad at 1.5 times the maximum recommended dose administered at day 28 of gestation and 24 hours prior to parturition. The data demonstrated that spinosyns were excreted in the milk of these dogs. Mortality and morbidity were greatest in puppies from the dam with the highest spinosyns level in milk. The spinosad milk: reference plasma exposure ratio calculated from this study ranged from 2.2 to 3.5.

In well-controlled field studies, COMFORTIS chewable tablets were administered safely in conjunction with other frequently used veterinary products, such as vaccines, anthelmintics, antibiotics, steroids, flea and tick control products, anesthetics, NSAIDs, antihistamines, alternative/herbal remedies, shampoos, and prescription diets. Changes in hematology, clinical chemistry and urinalysis values were compared pre-and post-study and were unremarkable.

STORAGE INFORMATION:

Store at 20-25°C (68 -77°F), excursions permitted between 15 to 30°C (59 to 86°F).

HOW SUPPLIED:

COMFORTIS chewable tablets are available in five flavored tablet sizes: 140, 270, 560, 810 or 1620 mg.

Each tablet size is available in color-coded packages of 6 tablets.

NADA 141-277, Approved by FDA

Manufactured for Elanco Animal Health,

A Division of Eli Lilly and Company,

Lilly Corporate Center, Indianapolis, IN 46285

PA9184DEAMP (V02-06-2009)

NDC 0986-4222-06

NDC 0986-4223-06

NDC 0986-4224-06

NDC 0986-4225-06

NDC 0986-4227-06

CA4222AM

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CA4224AM

CA4225AM

CA4227AM

Your veterinarian has chosen to prescribe COMFORTIS chewable tablets to meet your flea treatment and prevention needs.

Controlling fleas is very important to the health of your dog. Please read this leaflet, which describes the use of COMFORTIS chewable tablets to treat and prevent flea infestations. If you have any questions about this information, please consult your veterinarian. Additional information can be found at www.comfortis4dogs.com.

What are COMFORTIS chewable tablets?

COMFORTIS is a chewable, flavored tablet that you give to your dog to kill fleas and prevent flea infestations for one month.

COMFORTIS chewable tablets are for monthly use in dogs and puppies 14 weeks of age or older.

Why has my veterinarian prescribed COMFORTIS chewable tablets?

Your veterinarian has provided this medication to either prevent a flea infestation or to treat an existing infestation on your dog.

What should I discuss with my veterinarian regarding COMFORTIS chewable tablets for my dog?

Your veterinarian is your dog's healthcare expert and can make the best recommendation for medications for your dog. This includes the prevention and treatment of parasites such as fleas that may cause conditions that include flea allergy dermatitis, anemia, and other flea-related problems. Key points of your discussion may include the following:

- Treatment with COMFORTIS chewable tablets may begin at any time of the year, preferably starting one month before fleas become active and continuing through the end of flea season. In areas where fleas may occur year-round, monthly treatment with COMFORTIS chewable tablets should continue the entire year without interruption.
- If a dose is missed, administer COMFORTIS chewable tablets with food and resume a monthly dosing schedule.
- To minimize the likelihood of flea reinfestation, it is important to treat all animals within a household with an approved flea protection product.
- COMFORTIS chewable tablets are not for use in humans. Like all medications, keep COMFORTIS chewable tablets out of reach of children.

How should I give COMFORTIS chewable tablets to my dog?

Give COMFORTIS chewable tablets with food for maximum effectiveness.

COMFORTIS is a chewable tablet and is readily consumed by dogs when offered by the owner just prior to feeding. Alternatively, COMFORTIS chewable tablets may be offered in food or administered like other tablet medications.

Give COMFORTIS chewable tablets to your dog once a month. To help you remember the monthly dosing schedule, stick-on labels are included for your calendar.

What if I give more than the prescribed amount of COMFORTIS chewable tablets to my dog?

COMFORTIS chewable tablets have been tested in many types of dogs, and no severe adverse reactions have been reported. At elevated dose rates, the most severe adverse reaction observed was increased vomiting. However, in the event of possible overdose, contact your veterinarian, who is the healthcare expert for your dog.

Should I restrict either my dog's activity or contact with my dog after the tablet is consumed?

Since COMFORTIS chewable tablets are an oral formulation, you may maintain normal activities and interactions with your dog.

How quickly will COMFORTIS chewable tablets kill fleas?

In a laboratory study, COMFORTIS chewable tablets started to kill fleas within 30 minutes and killed 100% of the fleas within 4 hours. COMFORTIS chewable tablets kill fleas before they can lay eggs.

Does seeing fleas on my dog mean that the flea treatment is not working?

COMFORTIS chewable tablets kill fleas before they can lay eggs when used monthly according to the label directions. Remember that all animals in the household should be treated with an approved flea product to help control the flea population.

Female fleas that are living on animals produce eggs that fall from the animal into their surroundings. These eggs hatch within a week; larvae then emerge and spin cocoons to become pupae. The entire life cycle can be completed in as little as 3 weeks, with new adult fleas emerging from the pupae to jump onto your dog. Because each female flea can lay up to 50 eggs per day there is potential for a large build-up of eggs, larvae and pupae, resulting in a constant supply of new adults emerging in the dog's environment.

Regardless of the product used to kill the fleas, the dog can continue to be exposed to the fleas that live in the environment. When these fleas jump onto the dog, they will be quickly killed by COMFORTIS chewable tablets.

If within a month after your dog receives COMFORTIS chewable tablets you see fleas on your dog, it is most likely that these are new fleas that have very recently emerged from pupae and jumped onto the dog. These new fleas will quickly be killed before they can produce eggs that contaminate the environment.

Is it safe to give my dog COMFORTIS chewable tablets?

COMFORTIS chewable tablets have been demonstrated to be safe in pure and mixed breeds of healthy dogs when used according to label directions. Safety was established in puppies 14 weeks of age and older and adult dogs in both laboratory studies and clinical field studies. You should discuss the use of COMFORTIS chewable tablets with your veterinarian prior to use if your dog has a history of epilepsy (seizures).

Is it safe to give my breeding dogs COMFORTIS chewable tablets?

Use with caution in breeding females. You should discuss the use of COMFORTIS chewable tablets with your veterinarian prior to use in breeding females. Safe use of COMFORTIS chewable tablets in male dogs intended for breeding has not been evaluated.

What side effects might occur with COMFORTIS chewable tablets?

Like all medications, sometimes side effects may occur. In some cases, dogs vomited after receiving COMFORTIS chewable tablets.

If vomiting occurs within an hour of administration, redose with another full dose. During clinical studies, no severe or prolonged vomiting occurred. Additional adverse reactions observed in the clinical studies were decreased appetite, lethargy or decreased activity, diarrhea, cough, increased thirst, vocalization, increased appetite, redness of the skin, hyperactivity and excessive salivation. These reactions were regarded as mild and did not result in any dog being removed from the studies.

Since the introduction of COMFORTIS, additional side effects reported are incoordination, itching, trembling and seizures.

Can other medications be given while my dog is taking COMFORTIS chewable tablets?

Yes, COMFORTIS chewable tablets have been given safely with a wide variety of products and medications. Your veterinarian should be made aware of all products that you administered and/or intend to administer to your dog. For heartworm prevention, use products that are specifically prescribed by your veterinarian.

How should COMFORTIS chewable tablets be stored?

Store at 68-77°F (20-25°C). Temporary periods of time outside of this range between 59-86°F (15-30°C) are permitted.

If you have questions regarding the use of this product, consult your veterinarian, your dog's healthcare expert. For technical assistance or to report an adverse drug reaction, call 1-888-545-5973. Additional information can be found at www.comfortis4dogs.com.

PA9133DEAMP (V02-06-2009)

NDC 0986-4222-06

NDC 0986-4223-06

NDC 0986-4224-06

NDC 0986-4225-06

NDC 0986-4227-06

CA4222AM

CA4223AM

CA4224AM

CA4225AM

CA4227AM

PRINCIPAL DISPLAY PANEL

Comfortis 140 mg Bister

Comfortis (spinosad)

For Dogs and Puppies

14 weeks of age and older

5-10 lbs **140 mg**

(Give with a meal)

Puncture Here

Manufactured for Elanco Animal Health,

Indianapolis, IN 46285

Lot#
Exp.



Comfortis 140 mg Carton

FOR DOGS

5-10 lbs.

6 CHEWABLE TABLETS

140 mg

KILLS FLEAS FAST ACTING ONCE A MONTH

Comfortis® (spinosad)

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older

Starts killing fleas in 30 mins

Kills fleas before they can lay eggs

Give with a meal

HUMAN WARNING: NOT FOR HUMAN USE.

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN **APPROVED BY FDA** NADA 141-277

ELANCO™

For complete product information, see package insert. Questions? Consult your veterinarian. For pet's health care expert, call 1-888-545-5973 or visit www.comfortis4dogs.com. For technical assistance or to report an adverse drug experience, call 1-888-545-5973.

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JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT
NOV	DEC								

DOSE TRACKING CHART FOR:

Store at 20-25° C (68-77° F), excursions permitted between 15-30° C (59-86° F).
Comfortis chewable tablets with food for maximum effectiveness.
monthly at the recommended minimum dosage of 1.5 mg/lb (30 mg/kg). Administer once only once a month.

CAUTION: Comfortis chewable tablets kill fleas and are indicated for the prevention and treatment of flea infestations (Ctenocephalides felis) on dogs for one month.
Comfortis is a registered trademark of Elanco and Company.
Manufactured for Elanco Animal Health, A Division of El Lilly and Company, Indianapolis, IN 46205
www.comfortis4dogs.com
KEEP THIS AND ALL DOGS OUT OF THE REACH OF CHILDREN
Elanco

Comfortis
(spinosad)
Starts killing fleas in 30 minutes
Kills fleas before they can lay eggs
Give with a meal



Comfortis® (spinosad)

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.
KILLS FLEAS AND PREVENTS INFESTATIONS
For use in dogs and puppies 14 weeks of age and older

- Starts killing fleas in 30 mins.
- Kills fleas before they can lay eggs
- Give with a meal

HUMAN WARNING: NOT FOR HUMAN USE.
KEEP THIS AND ALL DOGS OUT OF THE REACH OF CHILDREN
APPROVED BY FDA
NDA 141-277



LOT NO:
EXP.



Comfortis – 140 mg Display Carton
FOR DOGS 5-10 lbs.
140 mg CHEWABLE TABLETS
Starts killing fleas in 30 mins
Kills fleas before they can lay eggs
Give with a meal

Comfortis® (spinosad)

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older

www.comfortis4dogs.com

ELANCO™



Comfortis 270 mg Bister

Comfortis (spinosad)

For Dogs and Puppies

14 weeks of age and older

10.1-20 lbs **270 mg**

(Give with a meal)

Puncture Here

Manufactured for Elanco Animal Health,

Indianapolis, IN 46285

Lot#

Exp.



Comfortis 270 mg Carton

FOR DOGS

10.1-20 lbs.

6 CHEWABLE TABLETS

270 mg

KILLS FLEAS FAST ACTING ONCE A MONTH

Comfortis® (spinosad) **Caution:** Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older

Starts killing fleas in 30 mins

Kills fleas before they can lay eggs

Give with a meal

HUMAN WARNING: NOT FOR HUMAN USE.

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN **APPROVED BY FDA** NADA 141-277

ELANCO™

For complete product information, see package insert. Questions? Consult your veterinarian. For pet's health care expert, call 1-888-545-5973 or visit www.comfortis4dogs.com. For technical assistance or to report an adverse drug experience, call 1-888-545-5973.

D	A	T	E	O	F	D	O	S	E
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NOV	DEC								

DOSE TRACKING CHART FOR:

Store at 20-25° C (68-77° F), excursions permitted between 15-30° C (59-86° F). Comfortis chewable tablets with food for maximum effectiveness. Administer monthly at the recommended minimum dosage of 1.5 mg/lb (30 mg/kg). Administer once only once a month.

SH8142DEANS
V02-06-2009
NDC 0986-4223-06
CA4223AM

- Starts killing fleas in 30 minutes
- Kills fleas before they can lay eggs
- Give with a meal

Comfortis
(spinosad)
Elanco
KEEP THIS AND ALL
DOGS OUT OF THE
REACH OF CHILDREN
www.comfortis4dogs.com
Indianapolis, IN 46205
A Division of Eli Lilly and Company
Lilly Corporate Center
Manufactured for Elanco Animal Health
Eli Lilly and Company
Comfortis is a registered trademark of
Eli Lilly and Company.
on dogs for one month.
of flea infestations (Ctenocephalides felis)
indicated for the prevention and treatment
Comfortis chewable tablets kill fleas and are
use by or on the order of a licensed veterinarian.
CAUTION: Federal (USA) law restricts this drug to
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FOR DOGS
10.1-20 lbs.
6 CHEWABLE
TABLETS
270 mg

FOR DOGS
10.1-20 lbs.
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FOR DOGS
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6 CHEWABLE
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FOR DOGS
10.1-20 lbs.
6 CHEWABLE
TABLETS
270 mg

Comfortis® (spinosad)

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.
KILLS FLEAS AND PREVENTS INFESTATIONS
For use in dogs and puppies 14 weeks of age and older

- Starts killing fleas in 30 mins.
- Kills fleas before they can lay eggs
- Give with a meal

HUMAN WARNING: NOT FOR HUMAN USE.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN
APPROVED BY FDA
NDA 141-277

Comfortis
(spinosad)
Elanco



Elanco **Comfortis**® (spinosad)



Comfortis – 270 mg Display Carton
FOR DOGS 10.1-20 lbs.
270 mg CHEWABLE TABLETS
Starts killing fleas in 30 mins
Kills fleas before they can lay eggs
Give with a meal

Comfortis® (spinosad)

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older

www.comfortis4dogs.com

ELANCO™



Comfortis 560 mg Biter

Comfortis (spinosad)

For Dogs and Puppies

14 weeks of age and older

20.1-40 lbs **560 mg**

(Give with a meal)

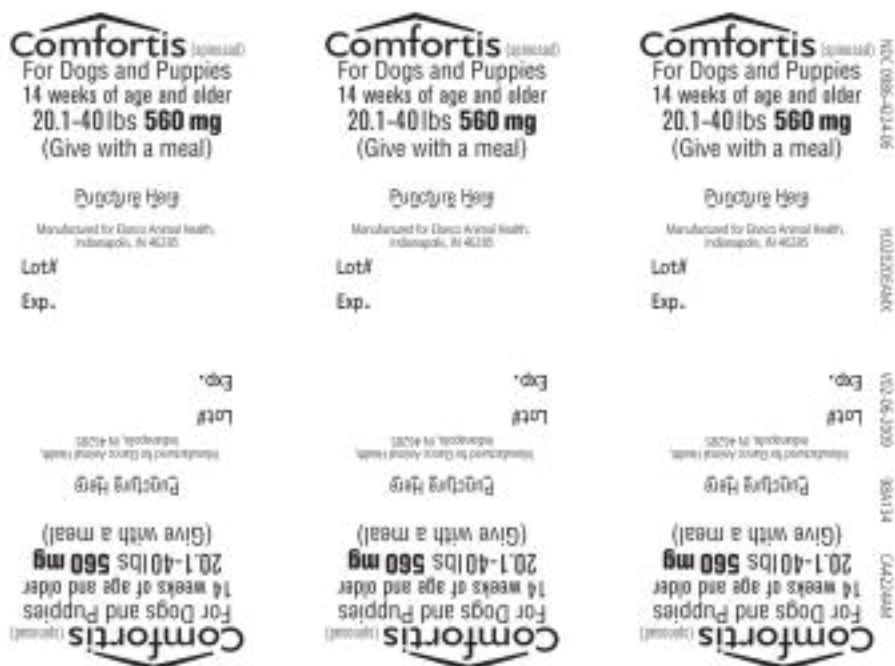
Puncture Here

Manufactured for Elanco Animal Health,

Indianapolis, IN 46285

Lot#

Exp.



Comfortis 560 mg Carton

FOR DOGS

20.1-40 lbs.

6 CHEWABLE TABLETS

560 mg

KILLS FLEAS FAST ACTING ONCE A MONTH

Comfortis® (spinosad) **Caution:** Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

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NOV	DEC								

DOSE TRACKING CHART FOR:

Store at 20-25° C (68-77° F), excursions permitted between 15-30° C (59-86° F). Comfortis chewable tablets with food for maximum effectiveness. Administer monthly at the recommended minimum dosage of 1.5 mg/lb (30 mg/kg). Administer only once a month.

SH815ZDEANS
V02-06-2009
NDC 0986-4224-06
C44224AM

- Starts killing fleas in 30 minutes
- Kills fleas before they can lay eggs
- Give with a meal

Comfortis®
(spinosad)
Elanco
Manufactured for Elanco Animal Health, A Division of Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46205
www.comfortis4dogs.com
KEEP THIS AND ALL DOGS OUT OF THE REACH OF CHILDREN
CAUTION: (See insert for instructions on use by or on the order of a licensed veterinarian.)
Comfortis chewable tablets kill fleas and are indicated for the prevention and treatment of flea infestations (Ctenocephalides felis) on dogs for one month.
Comfortis® is a registered trademark of Eli Lilly and Company.

FOR DOGS 20.1-40 lbs.
6 CHEWABLE TABLETS 560 mg



FOR DOGS 20.1-40 lbs.
6 CHEWABLE TABLETS 560 mg



FOR DOGS 20.1-40 lbs.
6 CHEWABLE TABLETS 560 mg




FOR DOGS 20.1-40 lbs.
6 CHEWABLE TABLETS 560 mg



Comfortis® (spinosad)

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.
KILLS FLEAS AND PREVENTS INFESTATIONS
For use in dogs and puppies 14 weeks of age and older

- Starts killing fleas in 30 mins.
- Kills fleas before they can lay eggs
- Give with a meal

HUMAN WARNING: NOT FOR HUMAN USE. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. APPROVED BY FDA. NDA 141-277

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Comfortis®
(spinosad)
Elanco



Elanco **Comfortis®** (spinosad)



Comfortis – 560 mg Display Carton
FOR DOGS 20.1-40 lbs.
560 mg CHEWABLE TABLETS
Starts killing fleas in 30 mins
Kills fleas before they can lay eggs
Give with a meal

Comfortis® (spinosad)

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older

www.comfortis4dogs.com

ELANCO™



Comfortis 810 mg Bister

Comfortis (spinosad)

For Dogs and Puppies

14 weeks of age and older

40.1-60 lbs **810 mg**

(Give with a meal)

Puncture Here

Manufactured for Elanco Animal Health,

Indianapolis, IN 46285

Lot#

Exp.



Comfortis 810 mg Carton

FOR DOGS

40.1-60 lbs.

6 CHEWABLE TABLETS

810 mg

KILLS FLEAS FAST ACTING ONCE A MONTH Comfortis® (spinosad)

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KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older

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Kills fleas before they can lay eggs

Give with a meal

HUMAN WARNING: NOT FOR HUMAN USE.

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN **APPROVED BY FDA NADA 141-277**

ELANCO™

For complete product information, see package insert. Questions? Consult your veterinarian. For pet's health care expert or call 1-888-545-5973 or visit www.comfortis4dogs.com. For technical assistance or to report an adverse drug experience, call 1-888-545-5973.

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KEEP THIS AND ALL DAUGS OUT OF THE REACH OF CHILDREN
Elanco



FOR DOGS 40.1-60 lbs.
6 CHEWABLE TABLETS 810 mg

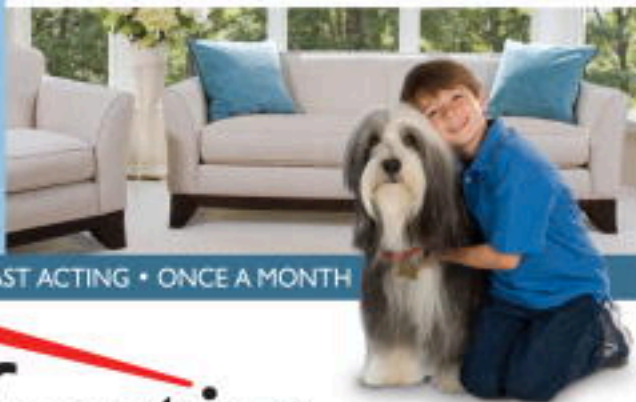


FOR DOGS 40.1-60 lbs.
6 CHEWABLE TABLETS 810 mg

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6 CHEWABLE TABLETS 810 mg



KILLS FLEAS • FAST ACTING • ONCE A MONTH



FOR DOGS 40.1-60 lbs.
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Comfortis® (spinosad)

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KILLS FLEAS AND PREVENTS INFESTATIONS
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Give with a meal

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KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN

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1 3 A 2 2 5



Elanco

Comfortis® (spinosad)



3 0 3 6 8 6 4 2 2 5 0 6 3

Comfortis – 810 mg Display Carton
FOR DOGS 40.1-60 lbs.
810 mg CHEWABLE TABLETS
Starts killing fleas in 30 mins
Kills fleas before they can lay eggs
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KILLS FLEAS AND PREVENTS INFESTATIONS

For use in dogs and puppies 14 weeks of age and older

www.comfortis4dogs.com

ELANCO™



Comfortis 1620 mg Bister

Comfortis (spinosad)

For Dogs and Puppies

14 weeks of age and older

60.1-120 lbs **1620 mg**

(Give with a meal)

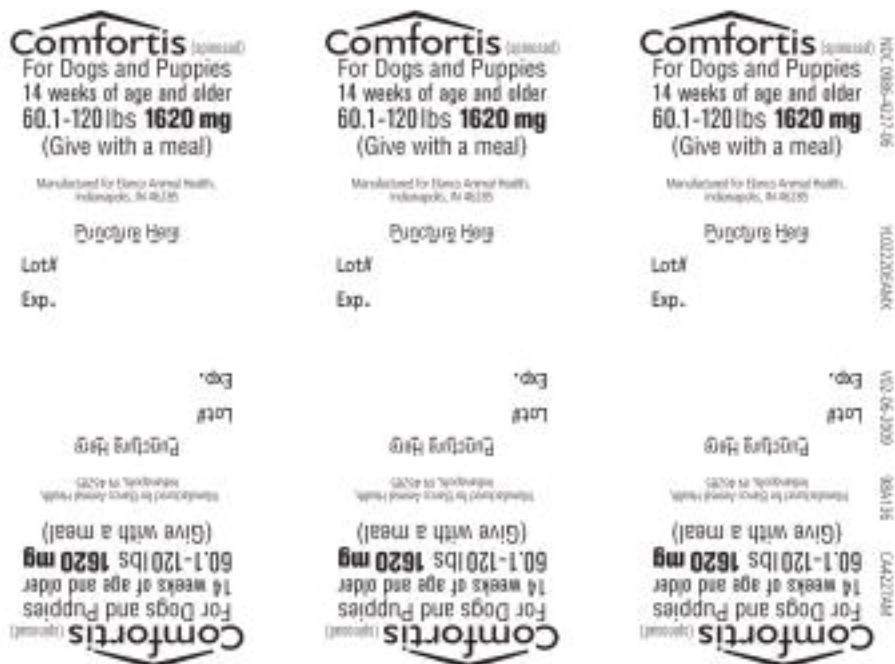
Puncture Here

Manufactured for Elanco Animal Health,

Indianapolis, IN 46285

Lot#

Exp.



Comfortis 1620 mg Carton

FOR DOGS

40.1-60 lbs.

6 CHEWABLE TABLETS

1620 mg

KILLS FLEAS FAST ACTING ONCE A MONTH

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KILLS FLEAS AND PREVENTS INFESTATIONS

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Kills fleas before they can lay eggs

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KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN **APPROVED BY FDA NADA 141-277**

ELANCO™

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